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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,046	09/27/1999	THOMAS MEADE	A-58634-6/RF	9059

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/405,046

Applicant(s)

MEADE ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22, 30, 32, 41, 42, 45, 48, 49 and 58-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 30, 32, 41, 42, 45, 48, 49, and 58-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/21/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 5/21/045 wherein a sequence listing was submitted and the claim status is as follows: claims 1-21, 23-29, 31, 33-40, 43-44, 46, 47, and 50-57 canceled; claims 22, 30, 32, 42, 45, and 48 amended; claims 59-66 added.

Note: Claims 22, 30, 32, 41, 42, 45, 48, 49, and 58-66 are pending.

RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election with traverse of Group I filed 5/21/04 is acknowledged. The traversal is on the ground(s) that the caspases of Group I and the interleukin-1 beta-converting enzyme of Group II, which is also known as capase-1, should be grouped together. This is found persuasive. Thus, the remaining Group have been viewed as an election without traverse. Hence, the remaining groups of the restriction requirement are still deemed proper and is therefore made FINAL.

Note: It is also duly noted that Applicant has elected the species Tyr-Val-Ala-Asp-Ala-Pro-Val that Applicant asserts is a peptide substrate known to be cleaved by caspase-1. The election was made without traverse.

112 REJECTIONS (New Matter and Written Description)

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 61, 62, 65, and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amendment filed 5/21/04, Applicant submitted a sequence listing and amended the claims to include specific sequences that are cleaved by caspase. However, review of the original specifications does not disclose any sequences. Thus, it is unclear where the specific sequences originated. Hence, Applicant is respectfully requested to point to the specific page and line number(s) wherein the sequences are disclosed.

5. Claims 22, 30, 32, 41, 42, 45, 48, 49, and 58-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims as written lack written description because they are directed to an unnamed peptide sequence that is cleaved by caspase. In particular, the claims as written require a person of ordinary skill in the art to engage in undue experimentation, with no assurance of success, in order to determine the peptide(s) encompassed by the instant invention. Furthermore pages 22-23, bridging paragraph, of the specification disclose that "the enzyme target substance is a protease, the blocking moiety may be a "peptide" or "polypeptide" which is capable of being cleaved by the target protease. By

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"peptide" or "polypeptide" herein is meant a compound of about 2 to about 15 amino acid residues covalently linked by peptide bonds. Preferred embodiments utilize polypeptides from about 2 to about 8 amino acids, with about 2 to about 4 being the most preferred. Preferably, the amino acids are naturally occurring amino acids, although amino acid analogs and peptidomimetic structures are also used. Under certain circumstances, the peptide may be only a single amino acid residue'. Hence, the specification does not describe the invention in such a way that one of ordinary skill would be able to ascertain what is being claimed. For example, a 'peptide' as defined in any standard chemical dictionary is a compound of 2-10 amino acids joined through the main chain by an amide bond. However, in Applicant's disclosure, the peptide may be a single amino acid or have about 15 amino acid residues. Thus, how Applicant has defined 'peptide' is not totally consistent with that known in the art. As a result, when looking to the specification for a concise description of exactly what is being claimed, the description is lacking.

112 REJECTIONS (Second Paragraph)

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 30, 32, 41, 48, 63 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because it is unclear what Applicant means by the phrase 'under conditions whereby said peptide interacts with caspase'. What

specific conditions are Applicant claiming that result in the peptide interacting with caspase in tissue, a cell, or a patient? Please clarify in order that one may ascertain what is being claimed.

103 REJECTIONS

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gries et al (US Patent No. 5,648,063).

Gries et al disclose compositions comprising a chelate complex for magnetic resonance imaging. The complexes comprise one or more elements having atomic numbers 21-29, 42, 44, or 57-83 (see entire document, especially, abstract; column 3, lines 49-61; column 5, lines 24-43). Possible biomolecules, which may be conjugated to the complexes, include peptides (column 4, lines 26-32). Conjugation may occur via a carboxyl group of the complexing acid or by a CH₂ group on a protein or peptide (column 4, lines 39-43). In column 23, Example 59, a solution of a gadolinium complex with DOTA and a monoclonal antibody is disclosed. While, Gries et al disclose a complex comprising a DOTA substituted with gadolinium and an antibody, the reference fails to disclose a complex comprising a DOTA substituted with gadolinium and a peptide. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Gries et al by replacing the

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monoclonal antibody with another targeting agent such as a peptide because, in column 4, lines 26-32, it is disclosed that possible biomolecules which maybe conjugated to the complexes of Gries et al include peptides. Furthermore, it is noted that a skilled practitioner in the art would recognize using any standard dictionary, e.g., Webster's Dictionary that a protease is any enzyme acts upon a peptide bond that results in splitting or hydrolyzing of that bond. Hence, any agent that is used for imaging that targets a specific location and generates an image has been 'activated'.

10. Claims 30, 32, 41, 42, 45, 48, 49, and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gries et al (US Patent No. 5,648,063) in view of Zychlinsky et al (US Patent No. 5,972,899).

Gries et al (see discussion above) fail to specifically disclose caspase (also known as interleukin -1beta-converting enzyme, ICE).

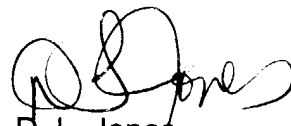
Zychlinsky et al disclose proteins and peptides that bind to interleukin-1beta-converting enzyme (ICE) to activate apoptosis (see entire document, especially, abstract; column 32, lines 17-51). Various linking groups may be conjugated to the to the ligand (column 20, lines 19-46).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Gries et al using the teachings of Zychlinsky et al and use a protease such as caspase because the prior art discloses that it is well known in the art to use caspase linked to ligands. In addition, a skilled practitioner in the art would recognize that caspase cleaves various biomolecules as taught by the cited prior art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


D. L. Jones
Primary Examiner
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August 9, 2004